REMARKS

The Office Action mailed April 23, 2001 (hereinafter the Office Action), has been received and reviewed. Claims 1 and 12 through 24 are currently pending in the application. Claims 1 and 12 through 24, however, stand rejected. Applicants have canceled claim 1 without prejudice or disclaimer, and Applicants have herein amended claims 12, 13, 15 through 19 and 21 through 24. Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

Double Patenting

Applicants respectfully request that the statutory double patenting rejection levied against claim 1 in the Office Action be withdrawn. In order to minimize expense and time delay, Applicants have herein canceled claim 1 without prejudice or disclaimer. As a result, Applicants respectfully submit that the double patenting rejection of claim 1 is no longer relevant and should be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 12, 14, 17, 18, 20, and 23 stand rejected under 35 U.S.C. § 102(b) (hereinafter "Section 102(b)") as being anticipated by Eckenhoff et al. (U.S. Patent 4,663,148). However, in order for a reference to anticipate a claim under Section 102(b) that references must expressly or inherently set forth each and every element recited in the claim. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Eckenhoff et al. fails to expressly or inherently teach each and every limitation recited in the rejected claims. In particular, Eckenhoff et al. fails to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation. Therefore, Applicants respectfully submit that the teachings of Eckenhoff et al. do not anticipate claims 12, 14, 17, 18, 20, and 23, and Applicants respectfully request that the rejection of claims 12, 14, 17, 18, 20, and 23 under Section 102(b) be withdrawn.

Claims 12 through 23 stand rejected under Section 102(b) as being anticipated by Wong et al. (U.S. Patent 5,324,280). However, Applicants respectfully submit that Wong et al. fails to expressly or inherently teach each and every limitation recited in the rejected claims. In particular, Wong et al. fails to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation.

Therefore, Applicants respectfully submit that the teachings of Wong et al. do not anticipate claims 12 through 23, and Applicants respectfully request that the rejection of claims 12 through 23 under Section 102(b) be withdrawn.

35 U.S.C. § 103(a) Obviousness Rejections

Pending claims 12 through 24 stand rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over either Eckenhoff et al. or Wong et al. A rejection under Section 103(a), however, is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that neither of the references cited in the Office Action provides evidence sufficient to properly establish the *prima facie* obviousness of any of claims 12 through 24. Thus, Applicants respectfully request that the rejections of claims 12 through 24 under Section 103 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The examiner bears the burden of establishing these three criteria based on the prior art, and, significantly, this burden can be met "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis added).

Applicants respectfully request that the rejection of claims 12 ,14, 17, 18, 20, and 23 under Section 103 as unpatentable over Eckenhoff et al. be withdrawn. The teachings of Eckenhoff et al. do not establish the *prima facie* obviousness of any of claims 12, 14, 17, 18, 20,

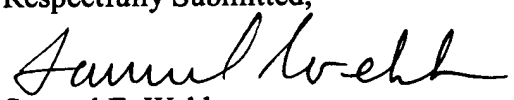
or 23. In particular, Eckenhoff et al. does not teach or suggest a dosage form including a self-emulsifying drug formulation, as is recited in each of claims 12, 14, 17, 18, 20, and 23. Therefore, Eckenhoff et al. fails to teach or suggest each of the limitations recited in claims 12, 14, 17, 18, 20, and 23, and, as a result, Applicants respectfully submit that the rejection of these claims as obvious in light of the teachings of Eckenhoff et al. should be withdrawn.

Applicants further request that the rejections of claims 12 through 24 under Section 103 as unpatentable over Wong et al. should be withdrawn. Wong et al. can not establish the *prima facie* obviousness of the dosage forms recited in claims 12 through 24. Like Eckenhoff et al., Wong fails to teach or suggest a dosage form including a self-emulsifying drug formulation. Therefore, Wong et al. fails to teach or suggest each and every limitation recited in claims 12 through 24, and, as a result, Applicants respectfully submit that the rejection of claims 12 through 24 as obvious in light of the teachings of Wong et al. should be withdrawn

CONCLUSION

Claims 12 through 24 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



Samuel E. Webb
Registration No.: 44,394
ALZA Corporation
Intellectual Property Department, M10-3
P.O. Box 7210
Mountain View, CA 94039
(650) 564-5106

Enclosures: Version With Markings to Show Changes Made

SEW/eg
Date: May 28, 2002

Version with Markings to Show Changes Made

Please cancel claim 1 without prejudice or disclaimer.

12. (Amended) A sustained-release, liquid formulation dosage form comprising:

a capsule comprising an expandable layer which expands upon contact with fluid; and

a [liquid,] self-emulsifying drug [layer consisting essentially of a drug, a surfactant, and a member selected from the group consisting of a mono- and di-glyceride] formulation.

13. (Amended) The dosage form of claim 12, wherein the expandable layer comprises an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose.

14. The dosage form of claim 13 comprising a semipermeable membrane surrounding the capsule and having an exit orifice formed or formable therein.

15. (Amended) The dosage form of claim 14, wherein the membrane comprises a cellulose acetate and a polyethylene glycol.

16. (Amended) The dosage form of claim 14, wherein the self emulsifying drug formulation comprises a drug [is] selected from the group consisting of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalmus gland, recombinant DNA, samatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chlorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotropic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

17. (Amended) The dosage form of claim 14, wherein the self-emusifying drug formulation comprises a surfactant [is] selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide,

polyoxyethylenated sorbitan monopalmitate comprising 20 [moles] moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 mules of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

18. (Amended) A sustained-release, liquid formulation dosage form comprising a capsule comprising an expandable layer which expands upon contact with fluid; and a [liquid,] self-emulsifying drug [layer consisting essentially of] formulation comprising a drug, a surfactant, and an oil selected from the group consisting of a vegetable, mineral, animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid, oleylester, glycolyzed ethoxylated glycerides of oils, fatty acids comprising 13 molecules of ethyleneoxide, and oleic acid decylester.

19. (Amended) The dosage form of claim 18, wherein the expandable layer comprises an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose.

20. The dosage form of claim 19 comprising a semipermeable membrane surrounding the capsule and having an exit orifice formed or formable therein.

21. (Amended) The dosage form of claim 20, wherein the semipermeable membrane comprises a cellulose acetate and a polyethylene glycol.

22. (Amended) The dosage form of claim 20, wherein the drug is selected from the group consisting of a peptide, protein, protein anabolic hormone, growth

promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalmus gland, recombinant DNA, samatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chlorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotropic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

23. (Amended) The dosage form of claim 20, wherein the surfactant is selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 mules of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

24. (Amended) The dosage form of claim 20, wherein the semipermeable membrane comprises a thermoplastic polymer composition having a softening point of 40°C to 180°C.